PATENT
082368-000000US
K4-004PCT-US

REMARKS/ARGUMENTS

I. Status of the Claims

After entry of this amendment, claims 1-4 and 12-14 are pending in this application, with claims 1-4 having been amended, claims 5-11 having been withdrawn as being directed to non-elected inventions, and new claims 12-14 having been added.

Amendments to the Specification

The Examiner noted the use of the trademark Tween in the specification. As requested by the Examiner, Applicants have amended the specification to capitalize the term Tween-20 whenever it appears and be accompanied by the generic terminology (polysorbate-20).

Amendments to the Claims

Claim 1 has been amended to more clearly define the claimed adjuvant. Support for the amendments to claim 1 are provided in the specification at, e.g., page 1, lines 6-10 and page 7, lines 10-22.

Claims 1-4 have been amended to delete "or a derivative thereof" (see rejection under 35 USC §112 below).

Claim 4 has been amended to add "purified" before hydroxyl unsaturated fatty acid (see rejection under 35 USC §112 below). Support is provided in claim 1.

New claims 12-14 directed to a method of enhancing the immunological activity of a vaccine have been added. Support for new claim 12 is provided in the specification at, e.g., page 15, lines 15-36. Support for new claim 13 is provided in the specification at, e.g., page 5, lines 12-18 and page 15, lines 15-36. Support for new claim 14 is provided in the specification at, e.g., page 11, lines 4-18 and page 15, lines 28-36.

No new matter is added by these amendments and new claims.

Rejoinder of Process Claims

In the restriction requirement, the Examiner stated that when an elected product claim is found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined and examined for patentability. Applicants herein add new process claims 12-14 that depend from the product claim 1. If the currently examined product claims become allowable, Applicant respectfully requests rejoinder of new claims 12-14.

II. Double Patenting

Claims 1-4 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of co-pending Application No. 10/363,484. Given that this is a provisional double patenting rejection, Applicants respectfully defer responding to this rejection until claims are determined to be allowable in this application and the co-pending application.

III. Claim Rejections

A. 35 USC §112

Claims 1-4 have been rejected as being indefinite. In particular, the Examiner alleges that claims 1-4 are rendered indefinite by use of the term "derivative thereof", and that claim 4 is rendered indefinite by use of the term "prepared from a medicinal plant". Applicants respectfully disagree.

Regarding the term "derivative thereof", the instant specification at page 7, lines 10-22 clearly describes what is meant by the term "derivative". To expedite prosecution, however, Applicants have amended claim 1 to clarify the meaning of "derivative", and have

deleted the terms "or a derivative thereof" and "or the derivative thereof" from claims 1-4, thereby rendering moot this ground of rejection.

Regarding the term "prepared from a medicinal plant", the instant specification at page 9, lines 29-34 clearly describes that the claimed fatty acids can be prepared from natural products including plants, or can be chemically synthesized. Based on this, the fatty acids are limited to "purified or synthesized" products as recited in amended claim 1. One skilled in the art would immediately recognize that "prepared from a medicinal plant" is only applied to "purified" fatty acid products and not to "synthesized" fatty acid products. To expedite prosecution, however, Applicants have amended claim 4 by adding the term "purified" before "hydroxy unsaturated fatty acids", thereby rendering moot this ground of rejection.

B. 35 USC §102

Claims 1-3 have been rejected as being anticipated by Lederer et al. (*J. Agroc. Food Chem.* 47:4611-4620, 1999) (Lederer). The Examiner cites Lederer as discussing 18 carbon hydroxy unsaturated fatty acids with the trihydroxy-monoene structure recited in claim 3.

Claims 1-4 have been rejected as being anticipated by Hamberg et al. (Plant Physiology, 110:807-815, 1996) (Hamberg). The Examiner cites Hamberg as discussing an 18 carbon hydroxy unsaturated fatty acid with the trihydroxy-monoene structure recited in claim 3, wherein the fatty acid is isolated from *Avena sativa* seed homogenates.

Claims 1-4 have been rejected as being anticipated by Miyaichi et al. (Nature Medicines, 49:24-28, 1005) (Miyaichi). The Examiner cites Miyaichi as discussing an 18 carbon hydroxy unsaturated fatty acid with the trihydroxy-monoene structure recited in claim 3, wherein the fatty acid is isolated from *Sparganii rhizona.*

Claims 1-3 have been rejected as being anticipated by Quinton et al. (Tetrahedron Letters 32:4909-4912, 1001) (Quinton). The Examiner cites Quinton as discussing 18 carbon hydroxy unsaturated fatty acids with the trihydroxy-monoene structure recited in claim 3.

The cited references, Lederer, Hamberg, Miyaichi and Quinton, do not teach every element of the rejected claims. According to MPEP 2131, a reference must teach every element to anticipate a claim. Claim 1 as amended reads on an adjuvant consisting essentially of an 18 carbon hydroxy unsaturated fatty acid and a pharmaceutically acceptable carrier. In each of the cited references, the 18 carbon hydroxy saturated fatty acids are present in solutions that are incompatible with pharmaceutical administration to an animal, that is, the disclosed fatty acids are in solutions/solvents/buffers that are not considered to be pharmaceutically acceptable carriers, as recited in amended claim 1.

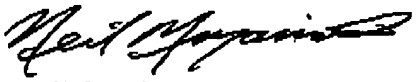
Lederer discusses 18 carbon hydroxy unsaturated fatty acids in solvents such as pyridine, DMF and diethyl ether (see Materials and Methods). Hamberg discusses 18 carbon hydroxy unsaturated fatty acids in a solvent such as methanol/chloroform (see Materials and Methods). Miyaichi discusses 18 carbon hydroxy unsaturated fatty acids extracted with methanol (see Chemical Experimental). Quinton discusses 18 carbon hydroxy unsaturated fatty acids produced in solvents such as benzoyl chloride, pyridine/dichloromethane, and potassium carbonate in methanol/water (see scheme 3 at page 4911). None of the above-mentioned solutions/solvents/buffers are compatible with pharmaceutical administration to an animal and, thus are not considered to be pharmaceutically acceptable carriers, as recited in amended claim 1.

Moreover, Miyaichi only discusses the 18 carbon hydroxy unsaturated fatty acid as one of 21 compounds in the crude drug called "Sableng", and does not disclose that this fatty acid is responsible for the drug's therapeutic effects. Thus, Miyaichi fails to disclose the need to formulate the 18 carbon hydroxy unsaturated fatty acid in a pharmaceutical composition as the sole active ingredient, as recited in amended claim 1.

Based on the foregoing, in which none of the cited references disclose the currently claimed composition, Applicants respectfully request that the rejection of claims 1-3 as being anticipated by Lederer and Quinton, and the rejection of claims 1-4 as being anticipated by Hamberg and Miyaichi, be withdrawn.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-324-2400.

Respectfully submitted,



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